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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/475,768	12/30/1999	PINAKI RAY	03764.P002	6849

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DARREN J. MILLIKEN
BLAKELY SOKOLOFF TAYLOR & ZAFMAN LLP
12400 WILSHIRE BOULEVARD
7TH FLOOR
LOS ANGELES, CA 90025

EXAMINER

WILLIAMS, CATHERINE SERKE

ART UNIT PAPER NUMBER

3763

DATE MAILED: 03/12/2004

18

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

09/475,768

Applicant(s)

RAY, PINAKI

Examiner

Catherine S. Williams

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--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 02 February 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
- ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
 - (b) ☐ they raise the issue of new matter (see Note below);
 - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____

3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: see attached remarks.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☐ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____

Claim(s) objected to: 9.

Claim(s) rejected: 1-8, 10-13, 48-60.

Claim(s) withdrawn from consideration: _____

8. ☐ The drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
10. ☐ Other: _____

Response to Arguments

Claims 1-5, 12, 13, 48-51, 53-56, 59 and 60 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Boddie (US Pat# 4,192,302). Applicant argues that “the Patent Office has not identified and Applicant is unable to find any teaching in Boddie of isolating an administered fluid between an upstream delivery conduit location and a downstream collection conduit location (for acquiring the administered fluid)”. Attention is drawn to the previous rejection, the figures of Boddie and the comments below.

The examiner admits that the previous rejection was brief and the figures of Boddie are small and crowded which makes understanding the prior art invention difficult. However, a solid understanding of anatomy and physiology in combination with the disclosure of Boddie enables one to see that the prior art reference clearly anticipates the instant invention.

Figure 1 of Boddie outlines flow to and from the major organ systems in the body. It is commonly understood that vessels that flow into an organ are considered being upstream to the organ and conversely vessels taking flow away from are considered downstream to the organ. Looking at figure 1, one can clearly see that the hepatic artery and portal vein are upstream vessels that flow into the liver and while not labeled the hepatic veins are the vessels that receive flow from the liver and return the flow eventually to the heart via the inferior vena cava.

With the above flow scheme in mind, attention is drawn to figure 3 of Boddie. The hepatic artery and portal vein (upstream vessels) are labeled and, as shown, receive branches 35 and 36 of catheter 34. Catheter 34 (delivery conduit) and branches 35 and 36 deliver chemotherapy agents 20 to the liver via these upstream channels. Ligatures T1 and T2

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conformably engage and releasably hold the first branch catheter 35 to the hepatic artery and the second branch catheter 36 to the portal vein.

Next, Boddie generally refers to means 40 “for selectively isolating the patient’s cancer-involved liver”. See 2:32-34 of Boddie. Catheter 41 in general shunts blood flow in the inferior vena cava from below the liver to above the liver (see ligatures T3 and T4) via outlet 43 of catheter 41 which is positioned in the right atrium of the heart. The important aspect of means 40 is that the region of the inferior vena cava between the ligatures T3 and T4 (collection seals) isolates the flow from the hepatic veins (area of vessel just before T4). Catheter 41 (collection conduit) has opening 44 that collects flow from the isolated region of the inferior vena cava (downstream channel) and returns the flow from the liver to the external flow path.

Applicant also argues “placing the collection conduit upstream (e.g. within the inferior vena cava as shown in Fig. 3 of Boddie) neither teaches or suggests placing the collection conduit adjacent to or in a downstream channel of the biological mass”. As explained above, the inferior vena cava is downstream of the hepatic veins. Blood flow from the hepatic veins does not go directly into the right atrium of the heart as described in applicant’s response.

The examiner is not sure why the previous rejection describes Boddie as teaching balloon inflation. However, none of the claims that recite a balloon were included in the 102 rejection. The ligatures of Boddie read on the limitation of a seal.

Regarding applicant’s request for a reference in support of the obvious rejection of claims 6-8, 52 and 57-58, see Aigner (US Pat# 4,540,402). Aigner clearly states that balloons are advantageous over ligatures for sealing a catheter to a vessel wall. See 4:42+.

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Regarding applicant's arguments with respect to claims 10-11, applicant is reminded that the instant claims are device claims and not method claims. Therefore, limited patentable weight is given to functional recitations in the claims. Additionally, applicant is reminded that the human body cannot be positively claimed since it is not patentable subject matter. However, Elliott (US Pat# 5,286,718) teaches methods for perfusion heart and liver due to tissue damage caused by, among other things, bypass surgery.

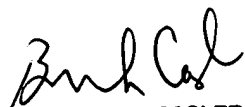
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine S. Williams whose telephone number is 703-308-4846. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 703-308-3552. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Catherine S. Williams *CSW*
March 8, 2004


BRIAN L. CASLER
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700